

**REMARKS****I. Status of the Claims**

Applicants have now canceled claims 20-25 from the application, and added new claim 26. Thus, only claim 26 is remaining in the case.

Applicants have also amended the heading "Peptide" in Table 1 on p. 16 to read "Peptide or Oligopeptide" so that the meaning of "peptide" in the specification is consistent with that stated on p. 9 whereby it is defined as "a peptide chain having a single peptide bond." A person skilled in the art would readily understand that the failure to include "or Oligopeptide" in this heading was an inadvertent error based on the prior definitions of the terms "peptide" and "oligopeptide". No new matter has been added.

**II. Claim Rejections – 35 U.S.C. § 112, Second Paragraph**

Claims 1 and 17-19 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite. The Examiner states that L-Arginine is not a peptide, oligopeptide or protein, contrary to the grouping in claim 1. Claims 1 and 17-19 have now been canceled, thereby rendering this ground of rejection moot with respect to these claims.

New claim 26 does not recite the use of L-Arginine. Thus, the Examiner's rejection in this respect does not apply.

**III. Claim Rejections - 35 U.S.C. § 112, First Paragraph - Enablement**

Claims 1 and 16-19 were rejected under 35 U.S.C. § 112, first paragraph, as not being enabled for preventing any disorder besides diabetes or gastrointestinal disorders. Claims 1 and 16-19 have now been canceled, thereby rendering this ground of rejection moot.

New claim 26 is directed to a method of treating diabetes or gastrointestinal disorders. The Examiner's rejection in this respect therefore does not apply.

**IV. Claim Rejections - 35 U.S.C. § 102****A. U.S. Patent No. 4,585,757**

Claims 1, 17, and 19 were rejected under 35 U.S.C. § 102(b) as being clearly anticipated by the '757 patent. The Examiner states that the '757 patent discloses the administration of bradykinin in the range of 50-500 µg/kg to lower blood pressure. As noted above, claims 1, 17, and 19 have been canceled from the application, thereby rendering the ground of rejection with respect to these claims moot.

New claim 26 is directed to a method of administering a peptide, oligopeptide or protein selected from the group consisting of Poly-Arginine, Des-Arg1-BK, BK fragment 1-7, [Lys1]-BK, Lys-BK, and Ile-Ser-BK for treating diabetes and gastrointestinal disorders. Since claim 26 does not recite the use of bradykinin, claim 26 is not anticipated by the '757 patent. Since the '757 patent does not teach or suggest the use of Applicants' other claimed compounds, claim 26 is also not rendered obvious by the '757 patent.

**B. U.S. Patent No. 4,152,425**

Claims 1, 17, and 19 were rejected under 35 U.S.C. § 102(b) as being anticipated by the '425 patent. The Examiner states that the '425 patent discloses the infusion of 10-3000µg bradykinin for treatment of shocks. Claims 1, 17, and 19 have been canceled from the application, thereby rendering the ground of rejection with respect to these claims moot.

New claim 26 is directed to a method of administering a peptide, oligopeptide or protein selected from the group consisting of Poly-Arginine, Des-Arg1-BK, BK fragment 1-7, [Lys1]-BK, Lys-BK, and Ile-Ser-BK for treating diabetes and gastrointestinal disorders. Since claim 26 does not recite the use of bradykinin, claim 26 is not anticipated by the '425 patent. Since the '425 patent does not teach or suggest the use of Applicants' other claimed compounds, claim 26 is also not rendered obvious by the '425 patent.

**C. Tobe et al.**

Claims 1, 17, and 19 were rejected under 35 U.S.C. 102(b) as being anticipated by Tobe et al. The Examiner states that Tobe et al. discloses the administration of bradykinin during

ischemia and the improvement in electrical stability of the bradykinin-treated hearts. Claims 1, 17, and 19 have been canceled from the application, thereby rendering the ground of rejection with respect to these claims moot.

New claim 26 is directed to a method of administering a peptide, oligopeptide or protein selected from the group consisting of Poly-Arginine, Des-Arg1-BK, BK fragment 1-7, [Lys1]-BK, Lys-BK, and Ile-Ser-BK for treating diabetes and gastrointestinal disorders. Since claim 26 does not recite the use of bradykinin, claim 26 is not anticipated by Tobe et al. Since Tobe et al. do not teach or suggest the use of Applicants' other claimed compounds, claim 26 is also not rendered obvious by Tobe et al.

**D. Uehara et al.**

Claims 1, 17-19 were rejected under 35 U.S.C. § 102(b) as being anticipated by Uehara et al. The Examiner states that Uehara et al. disclose the administration of bradykinin to diabetic mammals. Claims 1 and 17-19 have been canceled from the application, thereby rendering the ground of rejection with respect to these claims moot.

New claim 26 is directed to a method of administering a peptide, oligopeptide or protein selected from the group consisting of Poly-Arginine, Des-Arg1-BK, BK fragment 1-7, [Lys1]-BK, Lys-BK, and Ile-Ser-BK for treating diabetes and gastrointestinal disorders. Since claim 26 does not recite the use of bradykinin, claim 26 is not anticipated by Uehara et al. Since Uehara et al. do not teach or suggest the use of Applicants' other claimed compounds, claim 26 is also not rendered obvious by Uehara et al.

**E. Hartl et al. or Palitzsch et al.**

Claims 1, 17, and 19 were rejected under 35 U.S.C. § 102(b) as being anticipated by Hartl et al. or Palitzsch et al. The Examiner states that Hartl et al. disclose the administration of bradykinin to patients with gastrointestinal condition, and Palitzsch et al. disclose the administration of bradykinin to rats to treat ethanol induced vascular injury. Claims 1, 17, and 19 have been canceled from the application, thereby rendering the ground of rejection with respect to these claims moot.

New claim 26 is directed to a method of administering a peptide, oligopeptide or protein selected from the group consisting of Poly-Arginine, Des-Arg1-BK, BK fragment 1-7, [Lys1]-BK, Lys-BK, and Ile-Ser-BK for treating diabetes and gastrointestinal disorders. Since claim 26 does not recite the use of bradykinin, claim 26 is not anticipated by Hartl et al. or Palitzsch et al. Since neither Hartl et al. nor Palitzsch et al. teach or suggest the use of Applicants' other claimed compounds, claim 26 is also not rendered obvious by the cited references.

**F. U.S. Pat. No. 6,143,719**

Claims 1 and 17-19 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 6,143,719 ("the '719 patent"). The Examiner states that the '719 patent discloses the administration of BK or Seq. ID #19 to rabbits to prevent platelet aggregation in coronary thrombosis and stroke. Claims 1 and 17-19 have been canceled from the application, thereby rendering the ground of rejection with respect to these claims moot.

New claim 26 is directed to a method of administering a peptide, oligopeptide or protein selected from the group consisting of Poly-Arginine, Des-Arg1-BK, BK fragment 1-7, [Lys1]-BK, Lys-BK, and Ile-Ser-BK for treating diabetes and gastrointestinal disorders. Since claim 26 does not recite the use of bradykinin, claim 26 is not anticipated by the '719 patent. Since the '719 patent does not teach or suggest the use of Applicants' other claimed compounds, claim 26 is also not rendered obvious by the '719 patent.

**G. U.S. Pat. No. 4,177,261**

Claims 1 and 18 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 4,177,261 ("the '261 patent"). The Examiner states that the '261 patent discloses the administration of bradykinin or kallidin in order promote the healing of wounds. Claims 1 and 18 have been canceled from the application, thereby rendering the ground of rejection with respect to these claims moot.

New claim 26 is directed to a method of administering a peptide, oligopeptide or protein selected from the group consisting of Poly-Arginine, Des-Arg1-BK, BK fragment 1-7, [Lys1]-BK, Lys-BK, and Ile-Ser-BK for treating diabetes and gastrointestinal disorders. Since claim 26

does not recite the use of bradykinin, claim 26 is not anticipated by the '261 patent. Since the '261 patent does not teach or suggest the use of Applicants' other claimed compounds, claim 26 is also not rendered obvious by the '261 patent.

#### V. Claim Rejections - 35 U.S.C. § 103

Claims 1, 17, and 19 were rejected under 35 U.S.C. 103(a) as being unpatentable over Chahine. The Examiner states that Chahine et al. disclose the administration of bradykinin or des-Arg<sup>9</sup>-bradykinin to ischemic hearts to decrease fibrillation. Claims 1, 17, and 19 have been canceled from the application, thereby rendering the ground of rejection with respect to these claims moot.

New claim 26 is directed to a method of administering a peptide, oligopeptide or protein selected from the group consisting of Poly-Arginine, Des-Arg<sup>1</sup>-BK, BK fragment 1-7, [Lys<sup>1</sup>]-BK, Lys-BK, and Ile-Ser-BK for treating diabetes and gastrointestinal disorders. Chahine et al. do not teach or suggest the use of Applicants' claimed compounds, and therefore does not render claim 26 obvious.

#### VI. Conclusion

For the above reasons, it is believed that the present application is in a condition for allowability. Allowance is respectfully requested.

Please consider this a one-month extension of time and charge Deposit Account No. 26-0084 for the amount of \$55.00. No other fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any fees inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Respectfully submitted,

  
WENDY K. MARSH, Reg. No. 39,705  
McKEE, VOORHEES & SEASE, P.L.C.  
801 Grand Avenue, Suite 3200  
Des Moines, Iowa 50309-2721  
Phone No. (515) 288-3667  
Fax No. (515) 288-1338  
CUSTOMER NO: 22885  
Attorneys of Record

- WM -